UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,648	10/25/2001	Paul M. Sand	1759.17238-FOR	6512

26308 7590 04/11/2005

RYAN KROMHOLZ & MANION, S.C.
POST OFFICE BOX 26618
MILWAUKEE, WI 53226

EXAMINER	
COOLEY, CHARLES E	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,648	SAND, PAUL M.	
	Examiner	Art Unit	
	Charles E. Cooley	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9,15,17,18 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9,15,17,18 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL OFFICE ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 9, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronk (US 5,951,160 - already of record).

The patent to Ronk discloses a device in the embodiment of Figs. 8-10 comprising a receptacle 54 having an interior for receiving components 18, 20 of a bone filling material in an unmixed condition, the receptacle 54 including a first end region 62 and a second end region 60 oppositely spaced from the first end region 62; a mixing element 140 insertable into the interior of the receptacle 54 through the first end region 62 to mix the components; an actuator 128, 132 sized to be fitted to the first end region 62 (see Fig. 9) for operating the mixing element 140 to mix the components of the bone filling material within the interior of the receptacle 54; a dispenser outlet 58 formed adjacent the second end region 60 and communicating with the interior of the receptacle 54; a plunger 56 insertable into the interior of the receptacle 54 through the first end region and advanceable through the interior toward the second end region to dispense bone filling material through the dispenser outlet (col. 8, lines 53-67); wherein the mixing element 140 comprises a paddle 142 and/or 144 that mixes the components

in response to rotation; wherein the actuator 128, 132 rotates the paddle 142, 144; the mixing element 140 includes structure 154 and/or 156 to promote mixing of the components within the interior of the receptacle 54 and wherein the structure comprises a plurality of apertures 154; wherein the dispenser outlet comprises a Luer fitting 58 (col. 8, line 2); wherein the actuator is operable manually.

Moreover, and more specifically, the patent to Ronk discloses in FIGS. 8-9, a fourth embodiment of an apparatus 126 for packaging, mixing and delivering bone cement is shown. In this regard, like reference numerals will be used to identify similar structures as used with respect to the other preferred embodiments. The apparatus 126 operates similar to the apparatus 72 and 100 and also employs the syringe barrel 54 having the Luer fitting 58 and end cap 73 at the distal end 60 and the finger grip 62 at the proximal end 64. The apparatus 126 further includes an end cap 128 having a first cylindrical sidewall 130, a second cylindrical sidewall 132 and an annular shoulder 134 formed therebetween. Positioned adjacent to the end cap 128 is a wiper disk 136 having a cylindrical sidewall 138 that is substantially the same diameter as the first cylindrical sidewall 130. Fixed to the end cap 128 is a mixing prop 140 having a first arcuate blade 142 and a second arcuate blade 144. The mixing prop 140 further includes a cylindrical axial body 146 defining an axial bore 148. The axial bore 148 passes axially through the mixing prop 140 and the end cap 128 such that the bore 148 is operable to receive a cylindrical rod 150 having an enlarged end 152 similar to the mixing rod 86 or 114. Irrigation holes 154 also pass laterally through the cylindrical body 146 and into the axial bore 148.

In use, the apparatus 126 is again packaged in a sterile container and prepackaged with the first component 18. The syringe barrel or first container 54 is selectively sealed with the end cap 128 and cylindrical rod 150 as the cylindrical sidewall 130 is slidably and sealably received within the inner sidewall 82 of the syringe barrel 54. When it is desired to mix the bone cement, the sterile package is opened and the cylindrical rod 150 is grasped at the enlarged end 152 and slidably removed from the axial bore 148. The hypodermic needle 94 having the plurality of irrigation holes 96 is then slidably received within the axial bore 148. It should be noted that a bore may also be formed offset the end cap 128 for receipt of a shorter hypodermic needle 94. The second container or syringe 92 injects the second component 20 from the hypodermic needle 94 into the first component 18 within the first container 54, via the holes 154. After the second component 20 is delivered to the first component 18, the hypodermic needle 94 is slidably removed from the axial bore 148 and the cylindrical rod 150 is again used to seal the axial bore 148.

The second cylindrical sidewall 132 is then grasped by a user and rotated both clockwise and counter clockwise to axially rotate the mixing prop 140 within the first container 54. Notches 156 formed within the arcuate blades 142 and 144 enable the blades 142 and 144 to flex freely without being inhibited by the wiper disk 136. Upon rotating the mixing prop 140 in a first clockwise direction, the first and second arcuate blades 142 and 144 flex inward along the axial center line of the mixing prop 140. Upon rotating the mixing prop 140 in a second counter-clockwise direction, the blades 142 and 144 are flexed outward, as shown in FIG. 10. As the blades 142 and 144 flex

outwardly, the blades 142 and 144 scrap the inner sidewall 82 to provide further mixing of the first and second components 18 and 20.

Once the first and second components have been thoroughly mixed, the end cap 128 is slidably removed from the first container 54 and the wiper disk 136 is held adjacent to the proximal end 64. With the wiper disk 136 firmly held, the mixing prop 140 is slidably passed through an arcuate groove 158 formed within the wiper disk 136, thereby cleaning the mixing prop 140 as it slidably passes through the arcuate groove 158. The arcuate groove 158 is shaped to conform to the shape of the mixing prop 140 in its relaxed state so that the blades 142 and 144 align with the groove 158 when relaxed, via notches 156. Once removed, the plunger 56 is again inserted within the first container 54 to thereafter dispense the bone cement at the desired surgical site, via the distal end 60 or through a hypodermic needle attached to the male Luer fitting 58.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ronk (US 5,951,160) in view Berg et al. (US 3,546,129) or Lorenz et al. (US 4,294,293).

Ronk does not disclose the plunger having an opening. The patent to Berg et al. (US 3,546,129) discloses in Fig. 6 a receptacle 11' with a plunger 44 therein. The plunger has an opening 54 in communication with the interior of the receptacle. The patent to Lorenz et al. (US 4,294,293) discloses in Fig. 3 a receptacle 70 with a plunger 78 therein. The plunger has an opening 86 in communication with the interior of the receptacle. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the plunger of Ronk with an opening as disclosed by Berg et al. (US 3,546,129) or Lorenz et al. (US 4,294,293) for the purpose of controlling flow of material through the plunger (Berg et al.: col. 6, lines 48-75 and Lorenz et al.: col. 6, line 65 through col. 7, line 3).

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785).

Ronk does not disclose the stand. Solomon (US 5,842,786) discloses a mixing device 10 that includes a cylindrical member 12 having a hollow inside 14. The cylindrical member 12 has a mixing chamber 16 with an open upper end 17 and tapers to a lower reduced diameter end 18 defining a neck 19. The neck 19 serves as a dispensing nozzle for the bone cement and, if desired, may include extensions as is generally known in the art. The open upper end 17 is provided with a peripheral flange 20 which may be engaged by a surgeon to facilitate manual dispensing of the mixed cement therefrom through an opening 21 formed in the neck 19. A closure member 22

has a cylindrical shaft portion 24 with a diameter substantially equal to the inner diameter of the neck 19 to provide for a snug, frictional fit when the closure member 22 is inserted into the neck 19. The closure member 22 has a conical nose portion 26 at one end which, with the closure member 22 inserted fully into the neck 19, protrudes into the mixing chamber 16. An enlarged cap 28 is disposed at other end of the closure member 22 facilitating insertion and removal of the closure member 22 by a user. The closure member 22 may alternatively be threaded to the neck 19, or connected in any other conventional manner to hermetically seal off the same. A mixing subassembly, shown generally at 29, is slidable guidingly within the cylindrical member 12. The mixing subassembly 29 is inserted into the open upper end 17 of the cylindrical member 12, thereby substantially sealing the open upper end 17. The mixing subassembly 29 is repositionable within the cylindrical member 12 between a first relative position where the mixing subassembly 29 extends fully into the mixing chamber 16 and a second relative position where the mixing subassembly 29 is substantially withdrawn from the mixing chamber 16. The mixing subassembly 29 includes a member 30 and a mixing member 31 slidably receivable within the member 30 for movement between a first relative position where the mixing member 31 resides substantially within the member 30 and a second relative position where the mixing member 31 projects from the member 30 and into the mixing chamber 16. The member 30 reciprocates within the mixing chamber 16 and includes a cylindrical body 32 defining a holding chamber 33 and having a cap 34 at one end and a disc 36 rotatably mounted at the other end. The diameter of the cylindrical body 32 is selected so that the member 30 fits snugly but

slidably within the chamber 16 so that it may be guidingly axially displaced therein while substantially sealing the same. The cylindrical body 32 has a peripheral shoulder 38 within which the disc 36 nests. The disc 36 is held in place by a retaining wire 40 which frictionally fits in a groove 41 formed in the inner surface of the cylindrical body 32. It should be noted that the disc 36 may be rotatably mounted to the body 32 of the member 30 by any conventional mounting means which facilitates rotation of the disc 36 while securing the same to the body 32. The cylindrical body 32 is provided at its upper end with a flange 42. The surgeon is thus allowed to controllably displace the member 30 by grasping the flanges 20,42 as he/she would a conventional syringe, and pressuring the thumb against the flange 42 while holding the flange 20 with two fingers to thereby discharge the contents of the chamber portion 16. The mixing member 31 includes an elongate shaft portion 44 extending along an axis 45 and having a plurality of interdigitated paddles 46 extending radially alternatingly at diametrically opposite locations along the length of the shaft 44. The bottom portion of the shaft 44 has radial extensions 48 which are thicker than the paddles 46. The radial extensions 48 have contoured surfaces 50 generally conforming to the tapered inner surface portion 52 of the cylindrical member 12. A conical recess 54 is formed on the lower end of the shaft 44 and cooperates with the conical nose portion 26 of the closure member 22 with the mixing member 31 in its mixing position. The conical nose portion 26 of the closure member 22 provides a fulcrum on which the mixing member 31 rotates. The upper end of the shaft 44 includes an axial bore 56 and a cooperating radial opening 57 adapted to be connected to a means 58 for rotating the mixing member 31, such as a hand crank,

an electrical drill, a pneumatic drill, or any other conventional means for rotating the mixing member 31. As shown more particularly in FIGS. 2A-2C, the mixing member 31 may be attached to a hand crank 59 via an extension shaft 60. The extension shaft 60 may be inserted into the axial bore 56 and secured thereto by a cotter pin 61 extending through the opening 57 and a corresponding opening in the shaft 60. It should be noted that the extension shaft 60 may be connected to the mixing member 31 via any conventional means, or alternatively the shaft 60 and mixing member 31 may be formed as a single element. The hand crank 59 is keyed to the upper end of the shaft 60 via cooperating flat edges 62 which engage cooperating flat edges (not shown) on the upper end of the shaft 60. In a preferred form, the shaft 44 has a rectangular cross section and, more preferably, a square cross section, while the extension shaft 60 generally has a circular cross section and extends through a corresponding opening 63 in the cap 34. As shown more particularly in FIGS. 3A-3B, the rotating disc 36 has an opening 64 extending therethrough permitting the mixing member 31 to extend into the mixing chamber 16 during the mixing operation. The opening 64 generally includes a square opening portion 66, that is complementary to the square cross section of the shaft 44, with radial longitudinal slot-type opening portions 68 formed on opposite sides of the square opening portion 66, permitting the paddles 46 of the mixing member 31 to extend therethrough into the mixing chamber 16. The opening portion 66 and shaft 44 may have any cross-sectional shape, as long as they are complementary. The shaft 44 is thus keyed to the disc 36 so that rotation of the mixing member 31 about its lengthwise axis 45 effectuates rotation of the disc 36 with the mixing member 31 and

reciprocable member 30 in each of the first and second relative positions. It is important to note that since the radial extensions 48 at the lower end of the shaft 44 are thicker than the paddles 46, the upper end of the mixing member 31, including the attached extension shaft 60, must be directed upwardly through the rotating disc 36, before insertion of the reciprocable member 30, including the mixing member 31, into the cylindrical member 12. After inserting the mixing member 31 such that the shaft 60 projects from the opening 63 in the cap 34, the hand crank 59 may then be connected to the shaft 60. Referring now to FIG. 4, the mixing device 10 is shown with a powdered component 70 of a medical composition predisposed in the mixing chamber 16. The component 70 may be a powdered component of bone cement, such as a powdered mixture of polymethyl methacrylate, methyl methacrylate-styrene copolymer and barium sulfate, which is introduced into the mixing chamber 16 in a predetermined amount prior to assembling the medical device 10 for sale. After assembly, the medical device 10 may be placed in a hermetically sealed container 71 for sale to an end user. The cylindrical body 12 has a port 72 communicating in a radial direction with the mixing chamber 16. A removable cap 74 hermetically seals the port 72. When a surgeon wishes to use the mixing device 10, he/she removes the cap 74 and introduces into the mixing chamber 16, as shown more particularly in FIG. 5, the liquid component 76 of the bone cement, such as liquid methyl methacrylate monomer. This may be done using a conventional syringe, as shown at 78. Supplying the powdered component 70 of the bone cement already in the mixing chamber 16 eliminates the steps of disassembling the device 10 and pouring the powdered component 70 into the mixing chamber 16

through the open end 17 of the cylindrical member 12 and minimizes exposure of the same to ambient conditions. Applying the liquid component 76 of the bone cement through the port 72, instead of through open end 17, further minimizes ambient condition exposure. In a preferred form, the assembled medical device 10 is placed in the hermetically sealed container 71 along with a container, such as the syringe 78, containing the liquid component 76, such as liquid methyl methacrylate monomer, with the entire package being sold as a kit to an end user. After introduction of the liquid component 76 into the mixing chamber 16, the mixing member 31 is introduced within the mixing chamber 16 of the cylindrical member 12, as is shown in FIG. 6. The mixing member 31 is advanced into the mixing chamber 16 until the conical recess portion 54 receives the conical nose portion 26 of the closure member 22. In this fashion, it is assured that the paddles 46 will come in contact with the introduced cement components 70,76 contained in the mixing chamber 16 fully to the bottom of the mixing chamber portion 16. The mixing member 31 is now ready to be connected at its upper end to a suitable mixing apparatus such as a hand crank, electrical drill, pneumatic drill, and the like, for effectuating mixing. This may be accomplished by holding the mixing device 10 in the assembled condition in a stand for mixing by the appropriate mixing apparatus and keeping it there for the required amount of time, normally about 2-4 minutes. During the mixing operation, the powder 70 and liquid 76 components of the bone cement within the mixing chamber 16 are transformed into a thoroughly mixed and kneaded bone cement that is soft and pliable and thus ready for dispensing to fill a bone cavity and mechanically to fit a prosthesis. During mixing, all the effluent gases and

toxic fumes generated during the mixing of the two components will be withdrawn through the port 72 as generally indicated by arrow 79. To effectuate removal of the effluent gases and toxic fumes, the port 72 may be connected to a vacuum source, shown schematically at 80 in FIG. 6, via a vacuum tube 81. The port 72 is formed near the upper open end 17 of the cylindrical member 12 in an area above the level of the mixed bone cement such that mixed cement will not escape therethrough. In a preferred form, the cylindrical body 12 is made of a clear polymer which provides a user with the ability to control the speed of mixing while simultaneously viewing the mixture 70,76 in the mixing chamber 16. Being able to view the components 70,76 during mixing provides a user with a tactile sense of the consistency of the mixture 70,76 without having to actually touch the mixture 70,76 to determine its viscosity and thus exposing the mixture 70,76 to ambient conditions. Accordingly, a medical composition having desired properties may be consistently achieved. Once mixing is complete, the mixing member 31 is removed from the mixing chamber 16. Removal of the mixing member 31 is accomplished by simply pulling the mixing member 31 axially outward of the cylindrical member 12. No aligning of paddles 46 is necessary since the shaft 44 of the mixing member 31 is keyed to the disc 36 with the paddles 46 and slot-type opening portions 68 aligned. As the mixing member 31 is removed, the cooperating radial openings 68 in the rotating disc 36 scrape off any excess mixture of cement from the paddles 46. The mixing member 31 is pulled axially along the axis 45 until the radial extensions 48 contact the rotating disc 36. Since the radial extensions 48 are thicker than the paddles 46, the radial extensions 48 completely cover the radial openings 68 in

the disc 36 and thus provide a complete seal preventing any excess mixed cement from escaping into the reciprocating member 30. Following withdrawal of the mixing member 31 into the reciprocating member 30, the vacuum source 80 is disengaged from the port 72. As is previously noted, the port 72 is formed near the upper open end 17 of the cylindrical member 12, so as to find itself in an area well above the mixed bone cement. This is an area which is occupied by the reciprocating member 30 during the dispensing operation, and consequently no mixed cement will escape through the port 72 during the dispensing operation. The surgeon will then remove the closure member 22 from the neck 19 of the cylindrical member 12 by either pulling or unscrewing the closure member 22 from the neck 19. The dispensing operation may take place immediately by the surgeon's simply grasping the dispensing device 10 in the palm of his/her hand and with his/her thumb applying pressure on the flange 42 of the reciprocable member 30. While holding the flange 20 of the cylindrical member 12 firmly in his/her hand, he/she slowly and steadily axially displaces the reciprocable member 30 within the mixing chamber 16 toward the lower narrowed end 18, so as to dispense gradually the mixed bone cement through the opening 21 in the neck 19 into the bone situs. The surgeon, if he/she wishes, may utilize a mechanical force application system for the dispensing operation as shown in FIG. 7. The mixing device 10 may be positioned in a force apply device 84, which may be a caulking gun as shown, so as to position the flange 20 of the cylindrical member 12 in a front jaw 86 and the flange 42 of the reciprocable member 30 in a rear jaw 88. Then, as is well known, by taking the caulking gun 84 in hand, he/she may easily effect the axial displacement of the reciprocable member 30 within the

mixing chamber 16 cylindrical member 12 by pistol-gripping and moving two arms of the caulking gun 84 together, thus dispensing the mixed bone cement through the opening 21 the neck 19.

Solomon (US 4,227,184) disclose a disposable orthopedic implement is shown in perspective and in an exploded view in FIG. 1. These elements when assembled, as more fully described below, permit bone cement to be mixed in and dispensed from one and the same closed system, thereby avoiding undue exposure to ambient contaminants. The reference character 10 denotes the disposable orthopedic implement and it is shown as comprising a cylindrical member 20 which may be a barrel whose hollow inside 22 defines a chamber utilized for both mixing therein and dispensing therefrom the bone cement. This barrel 20 is shown having an open upper end 24 and a lower narrowed end 26, and is also provided with an open neck 25 which may be internally threaded. This lower narrowed end 26 of barrel 20 terminating in the neck 25 may serve in combination, as the dispensing nozzle for the bone cement mixer and dispenser 10. In the alternative, if desired, an extension tube 13 having an externally threaded portion 13a and an open bottom end as at 13b may be conveniently secured within the externally threaded neck 25, thereby extending in effect the dispensing nozzle by the length of the extension tube 13. In some instances, a surgeon may desire to utilize such an extension tube wherein the application of the cement in a particular cavity of the human body so requires it. During the mixing operation, the neck 25 is closed by a closure member 35 such as an externally threaded cap which may be conveniently secured within the internally threaded neck 25 so as to hermetically seal

off the same. As may be noted, closure member 35 is formed with a central depression 37 whose significance will more fully appear hereinafter. The open upper end 24 of the barrel 20 is peripherally provided with a flange portion 28 by means of which a surgeon, if manually operating the disposable orthopedic implement, will dispense the mixed cement therefrom through its open neck 25, as more fully described below. The member designed for reciprocation within the chamber 22 of the barrel 20 is preferably a plunger 30 whose diameter is designed so that the plunger fits snugly but slidably within the chamber 22 so that it may be axially displaced therein. As may be noted, the plunger at its upper end is also provided with a flange 38 which cooperates with the flange 28 of barrel 20 during the dispensing operation by allowing the surgeon to exert pressure on this flange 38 so as to axially displace the plunger 30 within the barrel 20. The bottom end of plunger 30 may be formed as shown, or if desired, it may be tapered so as to fit the lower narrowed end 26 of the barrel 20. When so tapered, plunger 30 may then better serve to evacuate the mixture of bone cement therefrom through the open neck 25. The plunger 30 is formed with an internal contoured opening 34 which, for the most part, is an axial channel that extends throughout the length thereof. Additionally there are formed tapered sections 36,36 communicating with the axial channel which sections 36,36 extend from about the center of the plunger 30 toward the bottom end thereof, substantially as shown. The function of this internal contoured opening 34 is to receive therein a mixing member 40 which essentially comprises a shaft consisting of a long top shaft section 44 and a short bottom shaft section 42. A pair of mixing paddles (vanes) 46,46 are provided adjacent the short bottom shaft

section 42 and radially extending from the shaft. These mixing paddles (vanes) 46,46 of the mixing member 40 are responsible for effecting the mixing operation within the chamber 22 of the cylindrical member 20 when assembled, as will be more apparent hereafter. Mixing member 40 is provided with two markers about its long top shaft section 44. The first marker 41 is located about the center portion of the shaft while the second marker 43 is located near its upper end portion, substantially as shown. These markers 41 and 43 are utilized during assembly of the mixing member 40 and the plunger 30 just prior to the commencement of the loading of the barrel 20 with the cement components and during and after the mixing operation, as will be more apparent from below. It is to be noted that the barrel 20 is also provided at its upper portion with a port 21 that is designed for attachment to a suitable vacuum source by means of a vacuum tube 19 so as to remove the effluent gas and any toxic fumes generated during the mixing operation of the cement components in chamber 22. It should also be noted that when a surgeon considers the need for using extension tube 13 as hereinabove mentioned, then plunger 30 will be displaced by the extension tube plunger 23 so as to dispense the mixed cement through the extension tube 13. The extension tube plunger has a shoulder region of increased diameter to engage the inner surface of the barrel in order to maintain its correct position within the barrel. Extension tube plunger 23 is essentially a cylindrical member having a solid bottom portion 23b and an upper flange 23a. It can otherwise be hollow. Again, the extension tube plunger 23 is designed with a diameter slightly less than the internal diameter of the extension tube 13 so as to snugly but slidably fit therein. Preferably, the surgeon will first utilize the plunger 30 to dispense

the already mixed cement from inside the chamber 22 into the extension tube 13 prior to the removal of plunger 30 and the introduction of the extension tube plunger 23 therein. In this fashion, the cement mixture already finds itself for the most part within the extension tube 13. As may also be noted, the mixing member 40 together with its vanes or paddles 46,46 and the internal contoured opening 34 formed within the plunger 30 are so designed that the long top shaft section 44 may be axially disposable within the contoured opening and, as long as paddles 46,46 remain clear of the tapered sections 36,36, the mixing member 40 may conveniently be rotated within the plunger 30 by the application of torque to the upper end of the shaft thereof projecting through plunger 30 beyond its flange 38. This torque is preferably exerted by either a pneumatic or an electric drill whose jaws may be removably attached thereto, as will be more fully described with reference to FIG. 3. These elements of the disposable orthopedic implement 10 shown in exploded perspective view and described with reference to FIG. 1, may conveniently be made, as by injection molding so as to form a rigid polymer, preferably a light transmitting rigid polymer, for example, an acrylic such as methyl methacrylate or an olefin such as polyethylene or polypropylene. Furthermore, it should be noted that these elements are designed for one use only and after use, they should be discarded. Also, all these elements are sterilizable and are sterilized prior to use. FIG. 2 is a perspective view of the various above-described elements of the disposable orthopedic implement 10 assembled in two subassemblies in condition for the introduction of the power and liquid components of the bone cement into the barrel by the utilization of a convenient funnel 18. It must be noted that just immediately prior

thereto, port 21 communicating with the hollow inside chamber 22 has been connected to a source of vacuum (not shown) by vacuum tube 19. This is to enable the removal from the chamber 22 of all of the effluent gas and toxic fumes that will be generated during the mixing of the two component parts of the bone cement therein. The first subassembly is of course effected by the application of the externally-threaded cap 35 representing the closure member to the internally-threaded open neck 25 of the barrel 20, hermetically sealing it off thereby. Bone cement is preferably prepared immediately prior to use as a mixture of a polymerizate, such as a liquid methyl methacrylate monomer and an activator such as a powdered mixture of polymethyl methacrylate, barium sulfate and benzoyl peroxide. The liquid cement portion is contained in an ampoule 14 and may have ten (10) ml or twenty (20)ml therein, depending upon the use, i.e., whether it is for a knee, requiring a small dose, or for a hip requiring a larger dose. The powder is normally packaged in a plastic pouch 16, again containing either 20 grams or 40 grams, depending whether it is going to be used with a 10 ml ampoule as a knee dose or with a 20 ml ampoule as a hip dose. These powders and liquids and the ampoules and pouches have been pre-sterilized when packaged in their respective containers. In the introduction of these bone cement component parts through the funnel 18, it is important to remember that first the powder contained in the pouch 16 must be introduced by emptying its contents through the funnel 18 into the hollow inside chamber 22 of the barrel before permitting the liquid cement component contained in ampoule 14 to be introduced therein. This introduction sequence is significant since immediately upon the introduction of the liquid component, the polymerization process

between the two bone cement components commences. Consequently, once the ampoule 14 has also been emptied into the hollow inside chamber 22 of the barrel, funnel 18 should be immediately withdrawn and the second subassembly represented by the combination of the plunger 30 with the mixing member 40 inserted therein, is then immediately introduced partly into the chamber 22 of the barrel 20 through its upper open end. It should be noted that the mixing member 40 has been introduced into the contoured opening 34 of the plunger 30 so that its upper marker 43 is just barely visible above the flange 38 thereof. This is significant since this allows the paddles or vanes 46,46 to remain clear of the tapered sections 36,36 also formed in the plunger 30, as previously mentioned. The plunger 30 together with its mixing paddle member 40 is introduced within the hollow inside chamber 22 of the barrel 20 until such time that its short bottom shaft section 42 comes to seat within the central depression 37 concentrically formed in the cap 35, as may be best observed in FIG. 3. In this fashion it is assured that paddles 46,46 come in contact with the introduced cement components 27 contained in the bottom part of the chamber 22, and also that the paddles 46,46 have a slight clearance for rotation above the cap 35. As may be noted in FIG. 3, the mixing paddle member 40 is now ready to be connected at the upper end of its long top shaft section 44 to the gripping jaws 52 of either a pneumatic or electric drill 50 for effecting the mixing operation. This may be accomplished by holding the disposable orthopedic implement 10 in this assembled condition in a stand for mixing by the pneumatic or electric drill 50 and keeping it there for the required amount of time, normally about 3 to 4 minutes. Under these circumstances, for example, the stand is

provided with a suitable support, by which implement 10 is snapped into place and a motor operating through gripping jaws 52 drives the upper end of the shaft 44 of the mixing member 40. During the mixing operation, the powder and liquid components 27 of the bone cement within the chamber 22 of the barrel 20 will be transformed to a thoroughly mixed and kneaded bone cement 39 that is soft and pliable and thus ready for dispensing to fill the bone cavity and mechanically to fix the prosthesis. As shown in FIG. 4, first the gripping jaws 52 of the pneumatic or electric drill 50 are disengaged from the upper end of the top shaft section 44 and then the mixing paddle member 40 is now completely introduced into the internal contoured opening 34 of the plunger 30 by simply gripping the shaft 44 and pulling at it until the marker 41 appears above flange 38. Of course, the mixing paddles 46,46 first will have to be aligned with the tapered sections 36,36, which can easily be accomplished by slightly rotating shaft 44 while also exerting a pulling force thereon. This complete introduction of the entire mixing member 40, in particular its mixing paddles or vanes 46,46 within the tapered sections 36,36 of the plunger 30 is important for two reasons. First, it permits the removal of any excess mixture of cement from the paddles 46,46 and, second it permits the quick and easy dispensing of the mixed cement 39 therefrom by already having accommodated the paddles 46,46, in the tapered sections 36,36. The resulting flush bottom surface of the plunger 30 now exerts a uniform extrusion force on the mixed bone cement 39. The surgeon is of course assured as to when the mixing paddle member 40 has been completely withdrawn within the contoured internal opening 34 of the plunger by observing the appearance of the second marker 41 on shaft 44 above the flange 38.

Following the disengagement of the shaft 44 and its withdrawal into the internal contoured opening 34 of the plunger 30, the vacuum source is also disconnected by removing the vacuum tube 19 from port 21. As may be noted from the figures, particularly FIG. 4, port 21 is formed near the upper open end 24 of the barrel 20 so as to find itself in the area well above the mixed bone cement 39, an area which is occupied by the plunger 30 during and immediately after the mixing operation, as may be best noted in FIGS. 3 and 4. Consequently, no mixed cement 39 may escape through this port 21 during the dispensing operation. The operator, who may well be the surgeon, will then remove the closure member 35 by unscrewing the same from the neck 25 and now the implement 10 is ready for applying the bone cement into a bone cavity of a patient. This dispensing operation may take place immediately by the surgeon's simply grasping the disposable orthopedic implement 10 in the palm of his hand and with his thumb applying pressure on the flange 38 of the plunger. While holding the other flange 28 of the cylindrical member 20 firmly in his hand, he slowly and steadily displaces axially the plunger 30 within the hollow inside chamber 22 toward its lower narrowed end 26, so as to dispense gradually the mixed bone cement 39 through the now open neck 25 into the bone situs. The surgeon, if he wishes, may utilize a mechanical force for the dispensing operation, as shown in FIG. 5. If so, the disposable orthopedic element 10 is first positioned within such a mechanical device, which may be a caulking gun as shown, so as to position the flange 28 of the barrel 20 in its front jaw and the flange 38 of the plunger 30 in its rear jaw. Then as is well known, by taking the caulking gun in hand, he may easily effect the axial displacement of the

plunger 30 within the cylindrical member 20 by pistol-gripping and moving the two arms of the caulking gun together.

Brown et al. (US 5,842,785) discloses in FIG. 1 a combined bone cement mixing and dispensing syringe. The cylindrical syringe body 1 defines a mixing chamber 2. A plunger 3 for ejecting the mixed cement is slidingly located in one end of the cylinder 1. A mixing element extends into the mixing chamber 2. The mixing element comprises a hollow shaft 4 along the central axis of the cylinder 1 with a number of fixed paddle blades 5 extending radially outwards from the shaft 4. The blades 5 are made of plastic strong enough to resist bending when mixing viscous cement. However, in order to prevent `dead spots` occurring and to ensure thorough mixing, diametrically opposite blades should have generally complementary shapes as shown. The shaft 4 is attached to a drive mechanism including a handle 7 and a gear mechanism which is indicated generally at 6 (shown in more detail in FIG. 2 and discussed further, below). The handle 7 carries a rod 8 which is axially movable by the handle 7. The rod 8 extends axially through the removable lid 9 of the cylinder 1 and passes through a drive bush 10 fixed to the mixing paddle shaft 4 and shown in more detail in FIG. 2. The handle 7 is preferably secured tightly to the rod 8 such that axial motion of the handle 7 necessarily results in rotation of the rod and hence the paddle shaft 4. The rod 8 of the preferred embodiment has a barley twist configuration of square cross-section. The rod 8 passes through the drive bush 10 via a correspondingly dimensioned square aperture 11 which functions as a driving lug. As the drive handle 7 is pushed, the rod 8 moves axially through aperture 11 and into the hollow shaft 4 of the mixing member. Thus, as the rod

8 moves axially through the aperture 11, the square shape of the aperture is forced to follow the `twist` of the rod 8, thus causing the bush 10, and mixing paddle to rotate as the handle 7 and hence the rod 8 are moved axially. Similarly, when the handle 7 is pulled the rod 8 is withdrawn through the aperture 11 in the bush 10 and the mixing member is caused to rotate in the opposite direction. Thus, as the handle is pushed and/or pulled the mixing blades 5 rotate within the mixing chamber about the axis of the shaft 4. The drive bush 10 is rotatably mounted inside the lid 9 and, in the embodiment of FIG. 1, the shaft 4 of the mixing member is fixedly attached to the drive bush 10. In the embodiment of FIG. 3, the mixing element is instead detachable from the lid assembly. Thus, the drive bush 10' has a number of locating ribs 100 around its outer periphery (FIG. 3A). The mixing member has a hollow shaft 4'. The top of the shaft 4' of the mixing member has a number of grooves 200, corresponding to the ribs 100, around its inner periphery. Towards the open end of the shaft 4', the grooves 200 open out to provide a widened entrance for the ribs 100. This enables easy push-fit location of the drive bush 101 in the shaft 4'. As in the first embodiment, the drive bush has an aperture shaped to cooperate with the rod 8 and translate axial movement of the rod into rotation of the mixing element. As shown in FIG. 3, the lid 9' carries a downwardly facing funnel shape guide member 201 which helps locate the top of shaft 4' to facilitate its engagement by the drive bush 10'. An O-ring seal 202 fitted into a groove on the exterior of shaft 4' cooperates between the top of shaft 4' and the inner surface of the neck of guide member 201 so as to prevent air entering the mixing chamber via the drive gear mechanism. The top end 203 of guide member 201 is fixed into a

downwardly projecting annular flange 204 of the lid 9' so as to retain the rotatable drive bush 10' within the lid assembly. A further O-ring seal 205 is disposed between the lid 9 and the exterior of cylinder 1. In the preferred embodiments, the mixing element has two diametrically opposite mixing blades 5 extending radially outwards from the shaft 4. Each blade 5 comprises alternate lobes 5a and spaces 5b along the length of the shaft 4. To ensure thorough mixing, the lobes 5a of one blade 5 correspond to the position of the spaces 5b of the other. Also, the lobes 5a themselves may be solid or apertured as shown. Apertured lobes minimize the amount of material required to form blades which provide sufficiently thorough mixing. Of course any number of blades 5 may be provided and the design of the blades may vary. For example, several blades of different widths could be used. The mixing chamber 2 is defined by a cylindrical syringe body 1, partially closed at one end. The closed end is adapted to axially receive a plunger 3, This end is also adapted to be received in stand 13 and may be secured to the stand 13 by corresponding screw threads. A seal 206 (FIG. 3) provides a seal between the syringe body 1 and stand 13. The other end of body 1 is preferably provided with an outer thread, adapted to receive a corresponding inner thread of the lid 9 and of a nozzle 12 (FIG. 4). In use, the cement materials to be mixed are placed into the mixing chamber 2, which is closed at one end by the plunger 3 or part of a plunger. The inner surface of the plunger 3 is preferably domed, as best seen from FIG. 4, to match the inner profile of the lid to minimize waste. The cylindrical body 1 may, after being filled to the desired level, be positioned on the stand 13 or may be hand-held. The lid 9 has an inner thread so that it can be screwed onto the thread at the end of the cylindrical

syringe body 1 with the shaft 4 and blades 5 extending into the cylinder 1. The cement is then thoroughly mixed by alternately pushing and pulling the handle 7 which causes the blades 5 to rotate about the axis of the shaft 4. Mixing may be carried out under vacuum and a vacuum pump may be attached to a vacuum port 16 in the lid 9. When the cement has been mixed sufficiently, the mixing member is removed. In the preferred embodiments, a slotted cover 14 (see also FIG. 5) is provided between the cylinder 1 and the lid 9. Cover 14 has a control aperture, through which the shaft 4 passes, and a slots. In the embodiment of FIG. 3, the paddle is initially left behind in the cylinder 1 after the rod 8 has been withdrawn. The drive bush 10' detaches from the top of the shaft 4' and may be removed when the lid assembly 9 is unscrewed. The paddle can then be withdrawn separately through the slot S in cover 14, the slot being of substantially the same width as the thickness of the blades 5 so that any cement remaining on the blades 5 is wiped off. In the embodiment of FIG. 1 the paddle is always removed with the handle and lid assembly. The lid 9 is then replaced by an applicator nozzle 12. The mixed cement is then forced through the nozzle 12 under the action of the plunger 3 to be applied to the appropriate site. Different types of plunger may be used to force the cement out through the nozzle 12 for example, a hand operated gun 17 may be used. However, the preferred embodiment uses a gas powered pressure gun. FIG. 4 shows the apparatus with a hand operated gun for imparting motion to plunger 3 and with a nozzle 12 attached in a dispensing position.

Accordingly, in view of the explicit teachings above in Solomon (US 5,842,786), Solomon (US 4,227,184) and Brown et al. (US 5,842,785) regarding a stand for

supporting a bone cement mixing receptacle, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the receptacle of Ronk (US 5,951,160) with a stand as taught by Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) for the purpose of supporting the mixing receptacle during the mixing operation. Furthermore, the underlined language added to claim 18 has been considered but is deemed but a method of operation or intended use of an apparatus that fails to impart or invoke any means or structure to the apparatus claims that defines over the applied prior art. The only structure in apparatus claim 18 is a stand to hold the receptacle which is clearly disclosed by the combination of references above.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ronk (US 5,951,160) in view Lampropoulos et al. (US 5,215,536) or Kirk (US 5,938,644).

Ronk does not disclose the receptacle having graduated markings. The patent to Lampropoulos et al. (US 5,215,536) teaches a receptacle 12 adapted for use with a plunger 14 therein. The receptacle 12 has graduations or indicia thereon (Fig. 1). Likewise, the patent to Kirk (US 5,938,644) discloses a receptacle 10 adapted for use with a plunger 20 therein. The receptacle 10 has graduations or indicia thereon (Fig. 1).

Accordingly, in view of the explicit teachings above in Lampropoulos et al. (US 5,215,536) or Kirk (US 5,938,644) regarding graduations on the receptacle with a plunger therein, it would have been obvious to one having ordinary skill in the art, at the

time applicant's invention was made, to have provided the receptacle of Ronk (US 5,951,160) with graduations as taught by Lampropoulos et al. (US 5,215,536) or Kirk (US 5,938,644) for the purpose of allowing the user to fill the receptacle with a prescribed amount of material, or alternatively to determine when a prescribed amount of fluid has been removed from an object (Lampropoulos et al.: col. 5, lines 10-15) or to indicate the capacity of the materiel to be administered (Kirk: col. 3, lines 65-67).

7. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785).

The patent to Ronk discloses a device in the embodiment of Figs. 8-10 comprising a receptacle 54 having an interior for receiving components 18, 20 of a bone filling material in an unmixed condition, the receptacle 54 including a first end region 62 and a second end region 60 oppositely spaced from the first end region 62; a mixing element 140 insertable into the interior of the receptacle 54 through the first end region 62 to mix the components; an actuator 128, 132 sized to be fitted to the first end region 62 (see Fig. 9) for operating the mixing element 140 to mix the components of the bone filling material within the interior of the receptacle 54; a dispenser outlet 58 formed adjacent the second end region 60 and communicating with the interior of the receptacle 54; a plunger 56 insertable into the interior of the receptacle 54 through the first end region and advanceable through the interior toward the second end region to dispense bone filling material through the dispenser outlet (col. 8, lines 53-67); wherein

the mixing element 140 comprises a paddle 142 and/or 144 that mixes the components in response to rotation; wherein the actuator 128, 132 rotates the paddle 142, 144; the mixing element 140 includes structure 154 and/or 156 to promote mixing of the components within the interior of the receptacle 54 and wherein the structure comprises a plurality of apertures 154; wherein the dispenser outlet comprises a Luer fitting 58 (col. 8, line 2); wherein the actuator is operable manually.

Moreover, and more specifically, the patent to Ronk discloses in FIGS. 8-9, a fourth embodiment of an apparatus 126 for packaging, mixing and delivering bone cement is shown. In this regard, like reference numerals will be used to identify similar structures as used with respect to the other preferred embodiments. The apparatus 126 operates similar to the apparatus 72 and 100 and also employs the syringe barrel 54 having the Luer fitting 58 and end cap 73 at the distal end 60 and the finger grip 62 at the proximal end 64. The apparatus 126 further includes an end cap 128 having a first cylindrical sidewall 130, a second cylindrical sidewall 132 and an annular shoulder 134 formed therebetween. Positioned adjacent to the end cap 128 is a wiper disk 136 having a cylindrical sidewall 138 that is substantially the same diameter as the first cylindrical sidewall 130. Fixed to the end cap 128 is a mixing prop 140 having a first arcuate blade 142 and a second arcuate blade 144. The mixing prop 140 further includes a cylindrical axial body 146 defining an axial bore 148. The axial bore 148 passes axially through the mixing prop 140 and the end cap 128 such that the bore 148 is operable to receive a cylindrical rod 150 having an enlarged end 152 similar to the

mixing rod 86 or 114. Irrigation holes 154 also pass laterally through the cylindrical body 146 and into the axial bore 148.

In use, the apparatus 126 is again packaged in a sterile container and prepackaged with the first component 18. The syringe barrel or first container 54 is selectively sealed with the end cap 128 and cylindrical rod 150 as the cylindrical sidewall 130 is slidably and sealably received within the inner sidewall 82 of the syringe barrel 54. When it is desired to mix the bone cement, the sterile package is opened and the cylindrical rod 150 is grasped at the enlarged end 152 and slidably removed from the axial bore 148. The hypodermic needle 94 having the plurality of irrigation holes 96 is then slidably received within the axial bore 148. It should be noted that a bore may also be formed offset the end cap 128 for receipt of a shorter hypodermic needle 94. The second container or syringe 92 injects the second component 20 from the hypodermic needle 94 into the first component 18 within the first container 54, via the holes 154. After the second component 20 is delivered to the first component 18, the hypodermic needle 94 is slidably removed from the axial bore 148 and the cylindrical rod 150 is again used to seal the axial bore 148.

The second cylindrical sidewall 132 is then grasped by a user and rotated both clockwise and counter clockwise to axially rotate the mixing prop 140 within the first container 54. Notches 156 formed within the arcuate blades 142 and 144 enable the blades 142 and 144 to flex freely without being inhibited by the wiper disk 136. Upon rotating the mixing prop 140 in a first clockwise direction, the first and second arcuate blades 142 and 144 flex inward along the axial center line of the mixing prop 140. Upon

rotating the mixing prop 140 in a second counter-clockwise direction, the blades 142 and 144 are flexed outward, as shown in FIG. 10. As the blades 142 and 144 flex outwardly, the blades 142 and 144 scrap the inner sidewall 82 to provide further mixing of the first and second components 18 and 20.

Once the first and second components have been thoroughly mixed, the end cap 128 is slidably removed from the first container 54 and the wiper disk 136 is held adjacent to the proximal end 64. With the wiper disk 136 firmly held, the mixing prop 140 is slidably passed through an arcuate groove 158 formed within the wiper disk 136, thereby cleaning the mixing prop 140 as it slidably passes through the arcuate groove 158. The arcuate groove 158 is shaped to conform to the shape of the mixing prop 140 in its relaxed state so that the blades 142 and 144 align with the groove 158 when relaxed, via notches 156. Once removed, the plunger 56 is again inserted within the first container 54 to thereafter dispense the bone cement at the desired surgical site, via the distal end 60 or through a hypodermic needle attached to the male Luer fitting 58.

However, Ronk does not disclose the stand. Solomon (US 5,842,786) discloses a mixing device 10 that includes a cylindrical member 12 having a hollow inside 14. The cylindrical member 12 has a mixing chamber 16 with an open upper end 17 and tapers to a lower reduced diameter end 18 defining a neck 19. The neck 19 serves as a dispensing nozzle for the bone cement and, if desired, may include extensions as is generally known in the art. The open upper end 17 is provided with a peripheral flange 20 which may be engaged by a surgeon to facilitate manual dispensing of the mixed cement therefrom through an opening 21 formed in the neck 19. A closure member 22

has a cylindrical shaft portion 24 with a diameter substantially equal to the inner diameter of the neck 19 to provide for a snug, frictional fit when the closure member 22 is inserted into the neck 19. The closure member 22 has a conical nose portion 26 at one end which, with the closure member 22 inserted fully into the neck 19, protrudes into the mixing chamber 16. An enlarged cap 28 is disposed at other end of the closure member 22 facilitating insertion and removal of the closure member 22 by a user. The closure member 22 may alternatively be threaded to the neck 19, or connected in any other conventional manner to hermetically seal off the same. A mixing subassembly, shown generally at 29, is slidable guidingly within the cylindrical member 12. The mixing subassembly 29 is inserted into the open upper end 17 of the cylindrical member 12, thereby substantially sealing the open upper end 17. The mixing subassembly 29 is repositionable within the cylindrical member 12 between a first relative position where the mixing subassembly 29 extends fully into the mixing chamber 16 and a second relative position where the mixing subassembly 29 is substantially withdrawn from the mixing chamber 16. The mixing subassembly 29 includes a member 30 and a mixing member 31 slidably receivable within the member 30 for movement between a first relative position where the mixing member 31 resides substantially within the member 30 and a second relative position where the mixing member 31 projects from the member 30 and into the mixing chamber 16. The member 30 reciprocates within the mixing chamber 16 and includes a cylindrical body 32 defining a holding chamber 33 and having a cap 34 at one end and a disc 36 rotatably mounted at the other end. The diameter of the cylindrical body 32 is selected so that the member 30 fits snugly but

slidably within the chamber 16 so that it may be guidingly axially displaced therein while substantially sealing the same. The cylindrical body 32 has a peripheral shoulder 38 within which the disc 36 nests. The disc 36 is held in place by a retaining wire 40 which frictionally fits in a groove 41 formed in the inner surface of the cylindrical body 32. It should be noted that the disc 36 may be rotatably mounted to the body 32 of the member 30 by any conventional mounting means which facilitates rotation of the disc 36 while securing the same to the body 32. The cylindrical body 32 is provided at its upper end with a flange 42. The surgeon is thus allowed to controllably displace the member 30 by grasping the flanges 20,42 as he/she would a conventional syringe, and pressuring the thumb against the flange 42 while holding the flange 20 with two fingers to thereby discharge the contents of the chamber portion 16. The mixing member 31 includes an elongate shaft portion 44 extending along an axis 45 and having a plurality of interdigitated paddles 46 extending radially alternatingly at diametrically opposite locations along the length of the shaft 44. The bottom portion of the shaft 44 has radial extensions 48 which are thicker than the paddles 46. The radial extensions 48 have contoured surfaces 50 generally conforming to the tapered inner surface portion 52 of the cylindrical member 12. A conical recess 54 is formed on the lower end of the shaft 44 and cooperates with the conical nose portion 26 of the closure member 22 with the mixing member 31 in its mixing position. The conical nose portion 26 of the closure member 22 provides a fulcrum on which the mixing member 31 rotates. The upper end of the shaft 44 includes an axial bore 56 and a cooperating radial opening 57 adapted to be connected to a means 58 for rotating the mixing member 31, such as a hand crank,

an electrical drill, a pneumatic drill, or any other conventional means for rotating the mixing member 31. As shown more particularly in FIGS. 2A-2C, the mixing member 31 may be attached to a hand crank 59 via an extension shaft 60. The extension shaft 60 may be inserted into the axial bore 56 and secured thereto by a cotter pin 61 extending through the opening 57 and a corresponding opening in the shaft 60. It should be noted that the extension shaft 60 may be connected to the mixing member 31 via any conventional means, or alternatively the shaft 60 and mixing member 31 may be formed as a single element. The hand crank 59 is keyed to the upper end of the shaft 60 via cooperating flat edges 62 which engage cooperating flat edges (not shown) on the upper end of the shaft 60. In a preferred form, the shaft 44 has a rectangular cross section and, more preferably, a square cross section, while the extension shaft 60 generally has a circular cross section and extends through a corresponding opening 63 in the cap 34. As shown more particularly in FIGS. 3A-3B, the rotating disc 36 has an opening 64 extending therethrough permitting the mixing member 31 to extend into the mixing chamber 16 during the mixing operation. The opening 64 generally includes a square opening portion 66, that is complementary to the square cross section of the shaft 44, with radial longitudinal slot-type opening portions 68 formed on opposite sides of the square opening portion 66, permitting the paddles 46 of the mixing member 31 to extend therethrough into the mixing chamber 16. The opening portion 66 and shaft 44 may have any cross-sectional shape, as long as they are complementary. The shaft 44 is thus keyed to the disc 36 so that rotation of the mixing member 31 about its lengthwise axis 45 effectuates rotation of the disc 36 with the mixing member 31 and

reciprocable member 30 in each of the first and second relative positions. It is important to note that since the radial extensions 48 at the lower end of the shaft 44 are thicker than the paddles 46, the upper end of the mixing member 31, including the attached extension shaft 60, must be directed upwardly through the rotating disc 36, before insertion of the reciprocable member 30, including the mixing member 31, into the cylindrical member 12. After inserting the mixing member 31 such that the shaft 60 projects from the opening 63 in the cap 34, the hand crank 59 may then be connected to the shaft 60. Referring now to FIG. 4, the mixing device 10 is shown with a powdered component 70 of a medical composition predisposed in the mixing chamber 16. The component 70 may be a powdered component of bone cement, such as a powdered mixture of polymethyl methacrylate, methyl methacrylate-styrene copolymer and barium sulfate, which is introduced into the mixing chamber 16 in a predetermined amount prior to assembling the medical device 10 for sale. After assembly, the medical device 10 may be placed in a hermetically sealed container 71 for sale to an end user. The cylindrical body 12 has a port 72 communicating in a radial direction with the mixing chamber 16. A removable cap 74 hermetically seals the port 72. When a surgeon wishes to use the mixing device 10, he/she removes the cap 74 and introduces into the mixing chamber 16, as shown more particularly in FIG. 5, the liquid component 76 of the bone cement, such as liquid methyl methacrylate monomer. This may be done using a conventional syringe, as shown at 78. Supplying the powdered component 70 of the bone cement already in the mixing chamber 16 eliminates the steps of disassembling the device 10 and pouring the powdered component 70 into the mixing chamber 16

through the open end 17 of the cylindrical member 12 and minimizes exposure of the same to ambient conditions. Applying the liquid component 76 of the bone cement through the port 72, instead of through open end 17, further minimizes ambient condition exposure. In a preferred form, the assembled medical device 10 is placed in the hermetically sealed container 71 along with a container, such as the syringe 78, containing the liquid component 76, such as liquid methyl methacrylate monomer, with the entire package being sold as a kit to an end user. After introduction of the liquid component 76 into the mixing chamber 16, the mixing member 31 is introduced within the mixing chamber 16 of the cylindrical member 12, as is shown in FIG. 6. The mixing member 31 is advanced into the mixing chamber 16 until the conical recess portion 54 receives the conical nose portion 26 of the closure member 22. In this fashion, it is assured that the paddles 46 will come in contact with the introduced cement components 70,76 contained in the mixing chamber 16 fully to the bottom of the mixing chamber portion 16. The mixing member 31 is now ready to be connected at its upper end to a suitable mixing apparatus such as a hand crank, electrical drill, pneumatic drill, and the like, for effectuating mixing. This may be accomplished by holding the mixing device 10 in the assembled condition in a stand for mixing by the appropriate mixing apparatus and keeping it there for the required amount of time, normally about 2-4 minutes. During the mixing operation, the powder 70 and liquid 76 components of the bone cement within the mixing chamber 16 are transformed into a thoroughly mixed and kneaded bone cement that is soft and pliable and thus ready for dispensing to fill a bone cavity and mechanically to fit a prosthesis. During mixing, all the effluent gases and

toxic fumes generated during the mixing of the two components will be withdrawn through the port 72 as generally indicated by arrow 79. To effectuate removal of the effluent gases and toxic fumes, the port 72 may be connected to a vacuum source, shown schematically at 80 in FIG. 6, via a vacuum tube 81. The port 72 is formed near the upper open end 17 of the cylindrical member 12 in an area above the level of the mixed bone cement such that mixed cement will not escape therethrough. In a preferred form, the cylindrical body 12 is made of a clear polymer which provides a user with the ability to control the speed of mixing while simultaneously viewing the mixture 70,76 in the mixing chamber 16. Being able to view the components 70,76 during mixing provides a user with a tactile sense of the consistency of the mixture 70,76 without having to actually touch the mixture 70,76 to determine its viscosity and thus exposing the mixture 70,76 to ambient conditions. Accordingly, a medical composition having desired properties may be consistently achieved. Once mixing is complete, the mixing member 31 is removed from the mixing chamber 16. Removal of the mixing member 31 is accomplished by simply pulling the mixing member 31 axially outward of the cylindrical member 12. No aligning of paddles 46 is necessary since the shaft 44 of the mixing member 31 is keyed to the disc 36 with the paddles 46 and slot-type opening portions 68 aligned. As the mixing member 31 is removed, the cooperating radial openings 68 in the rotating disc 36 scrape off any excess mixture of cement from the paddles 46. The mixing member 31 is pulled axially along the axis 45 until the radial extensions 48 contact the rotating disc 36. Since the radial extensions 48 are thicker than the paddles 46, the radial extensions 48 completely cover the radial openings 68 in

the disc 36 and thus provide a complete seal preventing any excess mixed cement from escaping into the reciprocating member 30. Following withdrawal of the mixing member 31 into the reciprocating member 30, the vacuum source 80 is disengaged from the port 72. As is previously noted, the port 72 is formed near the upper open end 17 of the cylindrical member 12, so as to find itself in an area well above the mixed bone cement. This is an area which is occupied by the reciprocating member 30 during the dispensing operation, and consequently no mixed cement will escape through the port 72 during the dispensing operation. The surgeon will then remove the closure member 22 from the neck 19 of the cylindrical member 12 by either pulling or unscrewing the closure member 22 from the neck 19. The dispensing operation may take place immediately by the surgeon's simply grasping the dispensing device 10 in the palm of his/her hand and with his/her thumb applying pressure on the flange 42 of the reciprocable member 30. While holding the flange 20 of the cylindrical member 12 firmly in his/her hand, he/she slowly and steadily axially displaces the reciprocable member 30 within the mixing chamber 16 toward the lower narrowed end 18, so as to dispense gradually the mixed bone cement through the opening 21 in the neck 19 into the bone situs. The surgeon, if he/she wishes, may utilize a mechanical force application system for the dispensing operation as shown in FIG. 7. The mixing device 10 may be positioned in a force apply device 84, which may be a caulking gun as shown, so as to position the flange 20 of the cylindrical member 12 in a front jaw 86 and the flange 42 of the reciprocable member 30 in a rear jaw 88. Then, as is well known, by taking the caulking gun 84 in hand, he/she may easily effect the axial displacement of the reciprocable member 30 within the

mixing chamber 16 cylindrical member 12 by pistol-gripping and moving two arms of the caulking gun 84 together, thus dispensing the mixed bone cement through the opening 21 the neck 19.

Solomon (US 4,227,184) disclose a disposable orthopedic implement is shown in perspective and in an exploded view in FIG. 1. These elements when assembled, as more fully described below, permit bone cement to be mixed in and dispensed from one and the same closed system, thereby avoiding undue exposure to ambient contaminants. The reference character 10 denotes the disposable orthopedic implement and it is shown as comprising a cylindrical member 20 which may be a barrel whose hollow inside 22 defines a chamber utilized for both mixing therein and dispensing therefrom the bone cement. This barrel 20 is shown having an open upper end 24 and a lower narrowed end 26, and is also provided with an open neck 25 which may be internally threaded. This lower narrowed end 26 of barrel 20 terminating in the neck 25 may serve in combination, as the dispensing nozzle for the bone cement mixer and dispenser 10. In the alternative, if desired, an extension tube 13 having an externally threaded portion 13a and an open bottom end as at 13b may be conveniently secured within the externally threaded neck 25, thereby extending in effect the dispensing nozzle by the length of the extension tube 13. In some instances, a surgeon may desire to utilize such an extension tube wherein the application of the cement in a particular cavity of the human body so requires it. During the mixing operation, the neck 25 is closed by a closure member 35 such as an externally threaded cap which may be conveniently secured within the internally threaded neck 25 so as to hermetically seal

off the same. As may be noted, closure member 35 is formed with a central depression 37 whose significance will more fully appear hereinafter. The open upper end 24 of the barrel 20 is peripherally provided with a flange portion 28 by means of which a surgeon, if manually operating the disposable orthopedic implement, will dispense the mixed cement therefrom through its open neck 25, as more fully described below. The member designed for reciprocation within the chamber 22 of the barrel 20 is preferably a plunger 30 whose diameter is designed so that the plunger fits snugly but slidably within the chamber 22 so that it may be axially displaced therein. As may be noted, the plunger at its upper end is also provided with a flange 38 which cooperates with the flange 28 of barrel 20 during the dispensing operation by allowing the surgeon to exert pressure on this flange 38 so as to axially displace the plunger 30 within the barrel 20. The bottom end of plunger 30 may be formed as shown, or if desired, it may be tapered so as to fit the lower narrowed end 26 of the barrel 20. When so tapered, plunger 30 may then better serve to evacuate the mixture of bone cement therefrom through the open neck 25. The plunger 30 is formed with an internal contoured opening 34 which, for the most part, is an axial channel that extends throughout the length thereof. Additionally there are formed tapered sections 36,36 communicating with the axial channel which sections 36,36 extend from about the center of the plunger 30 toward the bottom end thereof, substantially as shown. The function of this internal contoured opening 34 is to receive therein a mixing member 40 which essentially comprises a shaft consisting of a long top shaft section 44 and a short bottom shaft section 42. A pair of mixing paddles (vanes) 46,46 are provided adjacent the short bottom shaft

section 42 and radially extending from the shaft. These mixing paddles (vanes) 46,46 of the mixing member 40 are responsible for effecting the mixing operation within the chamber 22 of the cylindrical member 20 when assembled, as will be more apparent hereafter. Mixing member 40 is provided with two markers about its long top shaft section 44. The first marker 41 is located about the center portion of the shaft while the second marker 43 is located near its upper end portion, substantially as shown. These markers 41 and 43 are utilized during assembly of the mixing member 40 and the plunger 30 just prior to the commencement of the loading of the barrel 20 with the cement components and during and after the mixing operation, as will be more apparent from below. It is to be noted that the barrel 20 is also provided at its upper portion with a port 21 that is designed for attachment to a suitable vacuum source by means of a vacuum tube 19 so as to remove the effluent gas and any toxic fumes generated during the mixing operation of the cement components in chamber 22. It should also be noted that when a surgeon considers the need for using extension tube 13 as hereinabove mentioned, then plunger 30 will be displaced by the extension tube plunger 23 so as to dispense the mixed cement through the extension tube 13. The extension tube plunger has a shoulder region of increased diameter to engage the inner surface of the barrel in order to maintain its correct position within the barrel. Extension tube plunger 23 is essentially a cylindrical member having a solid bottom portion 23b and an upper flange 23a. It can otherwise be hollow. Again, the extension tube plunger 23 is designed with a diameter slightly less than the internal diameter of the extension tube 13 so as to snugly but slidably fit therein. Preferably, the surgeon will first utilize the plunger 30 to dispense

the already mixed cement from inside the chamber 22 into the extension tube 13 prior to the removal of plunger 30 and the introduction of the extension tube plunger 23 therein. In this fashion, the cement mixture already finds itself for the most part within the extension tube 13. As may also be noted, the mixing member 40 together with its vanes or paddles 46,46 and the internal contoured opening 34 formed within the plunger 30 are so designed that the long top shaft section 44 may be axially disposable within the contoured opening and, as long as paddles 46,46 remain clear of the tapered sections 36,36, the mixing member 40 may conveniently be rotated within the plunger 30 by the application of torque to the upper end of the shaft thereof projecting through plunger 30 beyond its flange 38. This torque is preferably exerted by either a pneumatic or an electric drill whose jaws may be removably attached thereto, as will be more fully described with reference to FIG. 3. These elements of the disposable orthopedic implement 10 shown in exploded perspective view and described with reference to FIG. 1, may conveniently be made, as by injection molding so as to form a rigid polymer, preferably a light transmitting rigid polymer, for example, an acrylic such as methyl methacrylate or an olefin such as polyethylene or polypropylene. Furthermore, it should be noted that these elements are designed for one use only and after use, they should be discarded. Also, all these elements are sterilizable and are sterilized prior to use. FIG. 2 is a perspective view of the various above-described elements of the disposable orthopedic implement 10 assembled in two subassemblies in condition for the introduction of the power and liquid components of the bone cement into the barrel by the utilization of a convenient funnel 18. It must be noted that just immediately prior

thereto, port 21 communicating with the hollow inside chamber 22 has been connected to a source of vacuum (not shown) by vacuum tube 19. This is to enable the removal from the chamber 22 of all of the effluent gas and toxic fumes that will be generated during the mixing of the two component parts of the bone cement therein. The first subassembly is of course effected by the application of the externally-threaded cap 35 representing the closure member to the internally-threaded open neck 25 of the barrel 20, hermetically sealing it off thereby. Bone cement is preferably prepared immediately prior to use as a mixture of a polymerizate, such as a liquid methyl methacrylate monomer and an activator such as a powdered mixture of polymethyl methacrylate, barium sulfate and benzoyl peroxide. The liquid cement portion is contained in an ampoule 14 and may have ten (10) ml or twenty (20)ml therein, depending upon the use, i.e., whether it is for a knee, requiring a small dose, or for a hip requiring a larger dose. The powder is normally packaged in a plastic pouch 16, again containing either 20 grams or 40 grams, depending whether it is going to be used with a 10 ml ampoule as a knee dose or with a 20 ml ampoule as a hip dose. These powders and liquids and the ampoules and pouches have been pre-sterilized when packaged in their respective containers. In the introduction of these bone cement component parts through the funnel 18, it is important to remember that first the powder contained in the pouch 16 must be introduced by emptying its contents through the funnel 18 into the hollow inside chamber 22 of the barrel before permitting the liquid cement component contained in ampoule 14 to be introduced therein. This introduction sequence is significant since immediately upon the introduction of the liquid component, the polymerization process

between the two bone cement components commences. Consequently, once the ampoule 14 has also been emptied into the hollow inside chamber 22 of the barrel, funnel 18 should be immediately withdrawn and the second subassembly represented by the combination of the plunger 30 with the mixing member 40 inserted therein, is then immediately introduced partly into the chamber 22 of the barrel 20 through its upper open end. It should be noted that the mixing member 40 has been introduced into the contoured opening 34 of the plunger 30 so that its upper marker 43 is just barely visible above the flange 38 thereof. This is significant since this allows the paddles or vanes 46,46 to remain clear of the tapered sections 36,36 also formed in the plunger 30, as previously mentioned. The plunger 30 together with its mixing paddle member 40 is introduced within the hollow inside chamber 22 of the barrel 20 until such time that its short bottom shaft section 42 comes to seat within the central depression 37 concentrically formed in the cap 35, as may be best observed in FIG. 3. In this fashion it is assured that paddles 46,46 come in contact with the introduced cement components 27 contained in the bottom part of the chamber 22, and also that the paddles 46,46 have a slight clearance for rotation above the cap 35. As may be noted in FIG. 3, the mixing paddle member 40 is now ready to be connected at the upper end of its long top shaft section 44 to the gripping jaws 52 of either a pneumatic or electric drill 50 for effecting the mixing operation. This may be accomplished by holding the disposable orthopedic implement 10 in this assembled condition in a stand for mixing by the pneumatic or electric drill 50 and keeping it there for the required amount of time, normally about 3 to 4 minutes. Under these circumstances, for example, the stand is

provided with a suitable support, by which implement 10 is snapped into place and a motor operating through gripping jaws 52 drives the upper end of the shaft 44 of the mixing member 40. During the mixing operation, the powder and liquid components 27 of the bone cement within the chamber 22 of the barrel 20 will be transformed to a thoroughly mixed and kneaded bone cement 39 that is soft and pliable and thus ready for dispensing to fill the bone cavity and mechanically to fix the prosthesis. As shown in FIG. 4, first the gripping jaws 52 of the pneumatic or electric drill 50 are disengaged from the upper end of the top shaft section 44 and then the mixing paddle member 40 is now completely introduced into the internal contoured opening 34 of the plunger 30 by simply gripping the shaft 44 and pulling at it until the marker 41 appears above flange 38. Of course, the mixing paddles 46,46 first will have to be aligned with the tapered sections 36,36, which can easily be accomplished by slightly rotating shaft 44 while also exerting a pulling force thereon. This complete introduction of the entire mixing member 40, in particular its mixing paddles or vanes 46,46 within the tapered sections 36,36 of the plunger 30 is important for two reasons. First, it permits the removal of any excess mixture of cement from the paddles 46,46 and, second it permits the quick and easy dispensing of the mixed cement 39 therefrom by already having accommodated the paddles 46,46, in the tapered sections 36,36. The resulting flush bottom surface of the plunger 30 now exerts a uniform extrusion force on the mixed bone cement 39. The surgeon is of course assured as to when the mixing paddle member 40 has been completely withdrawn within the contoured internal opening 34 of the plunger by observing the appearance of the second marker 41 on shaft 44 above the flange 38.

Following the disengagement of the shaft 44 and its withdrawal into the internal contoured opening 34 of the plunger 30, the vacuum source is also disconnected by removing the vacuum tube 19 from port 21. As may be noted from the figures, particularly FIG. 4, port 21 is formed near the upper open end 24 of the barrel 20 so as to find itself in the area well above the mixed bone cement 39, an area which is occupied by the plunger 30 during and immediately after the mixing operation, as may be best noted in FIGS. 3 and 4. Consequently, no mixed cement 39 may escape through this port 21 during the dispensing operation. The operator, who may well be the surgeon, will then remove the closure member 35 by unscrewing the same from the neck 25 and now the implement 10 is ready for applying the bone cement into a bone cavity of a patient. This dispensing operation may take place immediately by the surgeon's simply grasping the disposable orthopedic implement 10 in the palm of his hand and with his thumb applying pressure on the flange 38 of the plunger. While holding the other flange 28 of the cylindrical member 20 firmly in his hand, he slowly and steadily displaces axially the plunger 30 within the hollow inside chamber 22 toward its lower narrowed end 26, so as to dispense gradually the mixed bone cement 39 through the now open neck 25 into the bone situs. The surgeon, if he wishes, may utilize a mechanical force for the dispensing operation, as shown in FIG. 5. If so, the disposable orthopedic element 10 is first positioned within such a mechanical device, which may be a caulking gun as shown, so as to position the flange 28 of the barrel 20 in its front jaw and the flange 38 of the plunger 30 in its rear jaw. Then as is well known, by taking the caulking gun in hand, he may easily effect the axial displacement of the

plunger 30 within the cylindrical member 20 by pistol-gripping and moving the two arms of the caulking gun together.

Brown et al. (US 5,842,785) discloses in FIG. 1 a combined bone cement mixing and dispensing syringe. The cylindrical syringe body 1 defines a mixing chamber 2. A plunger 3 for ejecting the mixed cement is slidingly located in one end of the cylinder 1. A mixing element extends into the mixing chamber 2. The mixing element comprises a hollow shaft 4 along the central axis of the cylinder 1 with a number of fixed paddle blades 5 extending radially outwards from the shaft 4. The blades 5 are made of plastic strong enough to resist bending when mixing viscous cement. However, in order to prevent `dead spots` occurring and to ensure thorough mixing, diametrically opposite blades should have generally complementary shapes as shown. The shaft 4 is attached to a drive mechanism including a handle 7 and a gear mechanism which is indicated generally at 6 (shown in more detail in FIG. 2 and discussed further, below). The handle 7 carries a rod 8 which is axially movable by the handle 7. The rod 8 extends axially through the removable lid 9 of the cylinder 1 and passes through a drive bush 10 fixed to the mixing paddle shaft 4 and shown in more detail in FIG. 2. The handle 7 is preferably secured tightly to the rod 8 such that axial motion of the handle 7 necessarily results in rotation of the rod and hence the paddle shaft 4. The rod 8 of the preferred embodiment has a barley twist configuration of square cross-section. The rod 8 passes through the drive bush 10 via a correspondingly dimensioned square aperture 11 which functions as a driving lug. As the drive handle 7 is pushed, the rod 8 moves axially through aperture 11 and into the hollow shaft 4 of the mixing member. Thus, as the rod

8 moves axially through the aperture 11, the square shape of the aperture is forced to follow the `twist` of the rod 8, thus causing the bush 10, and mixing paddle to rotate as the handle 7 and hence the rod 8 are moved axially. Similarly, when the handle 7 is pulled the rod 8 is withdrawn through the aperture 11 in the bush 10 and the mixing member is caused to rotate in the opposite direction. Thus, as the handle is pushed and/or pulled the mixing blades 5 rotate within the mixing chamber about the axis of the shaft 4. The drive bush 10 is rotatably mounted inside the lid 9 and, in the embodiment of FIG. 1, the shaft 4 of the mixing member is fixedly attached to the drive bush 10. In the embodiment of FIG. 3, the mixing element is instead detachable from the lid assembly. Thus, the drive bush 10' has a number of locating ribs 100 around its outer periphery (FIG. 3A). The mixing member has a hollow shaft 4'. The top of the shaft 4' of the mixing member has a number of grooves 200, corresponding to the ribs 100, around its inner periphery. Towards the open end of the shaft 4', the grooves 200 open out to provide a widened entrance for the ribs 100. This enables easy push-fit location of the drive bush 101 in the shaft 4'. As in the first embodiment, the drive bush has an aperture shaped to cooperate with the rod 8 and translate axial movement of the rod into rotation of the mixing element. As shown in FIG. 3, the lid 9' carries a downwardly facing funnel shape guide member 201 which helps locate the top of shaft 4' to facilitate its engagement by the drive bush 10'. An O-ring seal 202 fitted into a groove on the exterior of shaft 4' cooperates between the top of shaft 4' and the inner surface of the neck of guide member 201 so as to prevent air entering the mixing chamber via the drive gear mechanism. The top end 203 of guide member 201 is fixed into a

downwardly projecting annular flange 204 of the lid 9' so as to retain the rotatable drive bush 10' within the lid assembly. A further O-ring seal 205 is disposed between the lid 9 and the exterior of cylinder 1. In the preferred embodiments, the mixing element has two diametrically opposite mixing blades 5 extending radially outwards from the shaft 4. Each blade 5 comprises alternate lobes 5a and spaces 5b along the length of the shaft 4. To ensure thorough mixing, the lobes 5a of one blade 5 correspond to the position of the spaces 5b of the other. Also, the lobes 5a themselves may be solid or apertured as shown. Apertured lobes minimize the amount of material required to form blades which provide sufficiently thorough mixing. Of course any number of blades 5 may be provided and the design of the blades may vary. For example, several blades of different widths could be used. The mixing chamber 2 is defined by a cylindrical syringe body 1, partially closed at one end. The closed end is adapted to axially receive a plunger 3, This end is also adapted to be received in stand 13 and may be secured to the stand 13 by corresponding screw threads. A seal 206 (FIG. 3) provides a seal between the syringe body 1 and stand 13. The other end of body 1 is preferably provided with an outer thread, adapted to receive a corresponding inner thread of the lid 9 and of a nozzle 12 (FIG. 4). In use, the cement materials to be mixed are placed into the mixing chamber 2, which is closed at one end by the plunger 3 or part of a plunger. The inner surface of the plunger 3 is preferably domed, as best seen from FIG. 4, to match the inner profile of the lid to minimize waste. The cylindrical body 1 may, after being filled to the desired level, be positioned on the stand 13 or may be hand-held. The lid 9 has an inner thread so that it can be screwed onto the thread at the end of the cylindrical

syringe body 1 with the shaft 4 and blades 5 extending into the cylinder 1. The cement is then thoroughly mixed by alternately pushing and pulling the handle 7 which causes the blades 5 to rotate about the axis of the shaft 4. Mixing may be carried out under vacuum and a vacuum pump may be attached to a vacuum port 16 in the lid 9. When the cement has been mixed sufficiently, the mixing member is removed. In the preferred embodiments, a slotted cover 14 (see also FIG. 5) is provided between the cylinder 1 and the lid 9. Cover 14 has a control aperture, through which the shaft 4 passes, and a slots. In the embodiment of FIG. 3, the paddle is initially left behind in the cylinder 1 after the rod 8 has been withdrawn. The drive bush 10' detaches from the top of the shaft 4' and may be removed when the lid assembly 9 is unscrewed. The paddle can then be withdrawn separately through the slot S in cover 14, the slot being of substantially the same width as the thickness of the blades 5 so that any cement remaining on the blades 5 is wiped off. In the embodiment of FIG. 1 the paddle is always removed with the handle and lid assembly. The lid 9 is then replaced by an applicator nozzle 12. The mixed cement is then forced through the nozzle 12 under the action of the plunger 3 to be applied to the appropriate site. Different types of plunger may be used to force the cement out through the nozzle 12 for example, a hand operated gun 17 may be used. However, the preferred embodiment uses a gas powered pressure gun. FIG. 4 shows the apparatus with a hand operated gun for imparting motion to plunger 3 and with a nozzle 12 attached in a dispensing position.

Accordingly, in view of the explicit teachings above in Solomon (US 5,842,786), Solomon (US 4,227,184) and Brown et al. (US 5,842,785) regarding a stand for

supporting a bone cement mixing receptacle, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the receptacle of Ronk (US 5,951,160) with a stand as taught by Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) for the purpose of supporting the second end of the mixing receptacle such that the first end of the receptacle is upright during the mixing operation.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) as applied to claim 21 above, and further in view of Berg et al. (US 3,546,129) or Lorenz et al. (US 4,294,293).

Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) do not disclose the plunger having an opening. The patent to Berg et al. (US 3,546,129) discloses in Fig. 6 a receptacle 11' with a plunger 44 therein. The plunger has an opening 54 in communication with the interior of the receptacle. The patent to Lorenz et al. (US 4,294,293) discloses in Fig. 3 a receptacle 70 with a plunger 78 therein. The plunger has an opening 86 in communication with the interior of the receptacle. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the plunger of Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) with an opening as disclosed by Berg et al. (US 3,546,129) or Lorenz

et al. (US 4,294,293) for the purpose of controlling flow of material through the plunger (Berg et al.: col. 6, lines 48-75 and Lorenz et al.: col. 6, line 65 through col. 7, line 3).

9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) as applied to claim 21 above, and further in view of Lampropoulos et al. (US 5,215,536) or Kirk (US 5,938,644).

Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) do not disclose the receptacle having graduated markings. The patent to Lampropoulos et al. (US 5,215,536) teaches a receptacle 12 adapted for use with a plunger 14 therein. The receptacle 12 has graduations or indicia thereon (Fig. 1). Likewise, the patent to Kirk (US 5,938,644) discloses a receptacle 10 adapted for use with a plunger 20 therein. The receptacle 10 has graduations or indicia thereon (Fig. 1). Accordingly, in view of the explicit teachings above in Lampropoulos et al. (US 5,215,536) or Kirk (US 5,938,644) regarding graduations on the receptacle with a plunger therein, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the receptacle of Ronk (US 5,951,160) in view Solomon (US 5,842,786), Solomon (US 4,227,184) or Brown et al. (US 5,842,785) with graduations as taught by Lampropoulos et al. (US 5,215,536) or Kirk (US 5,938,644) for the purpose of allowing the user to fill the receptacle with a prescribed amount of material, or alternatively to determine when a prescribed amount

of fluid has been removed from an object (Lampropoulos et al.: col. 5, lines 10-15) or to indicate the capacity of the materiel to be administered (Kirk: col. 3, lines 65-67).

Response to Amendment

10. Applicant's arguments with respect to the pending claims have been considered but are deemed to be moot in view of the new grounds of rejection necessitated by amendment. Applicant's claimed invention yet again reads on the prior art of record as set forth above.

Applicant is reminded that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Turning to the rejection of the claims under 35 U.S.C. § 102(b), it is noted that the terminology in a pending application's claims is to be given its broadest reasonable interpretation (*In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)) and limitations from a pending application's specification will not be read into the claims (*Sjolund v. Musland*, 847 F.2d 1573, 1581-82, 6 USPQ2d 2020, 2027 (Fed. Cir. 1988)).

Anticipation under 35 U.S.C. § 102(b) is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of a claimed invention. *See Constant v. Advanced Micro-Devices. Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1064 (Fed. Cir.), cert. denied, 488 U.S. 892 (1988); *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or the recognition of properties that are inherently possessed by the prior art reference. *Verdegaal Brothers Inc. v. Union Oil co. of California*, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987), cert. denied, 484 U.S. 827 (1987). A prior art reference anticipates the subject matter of a claim when that reference discloses each and every element set forth in the claim (*In re Paulsen*, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) and *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)); however, the law of anticipation does not require that the reference teach what Applicant is claiming, but only that the claims "read on" something disclosed in the reference. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984) (and overruled in part on another issue), *SRI Intel v. Matsushita Elec. Corp. Of Am.*, 775 F.2d 1107, 1118, 227 USPQ 577, 583 (Fed. Cir. 1985). Also, a reference anticipates a claim if it discloses the claimed invention such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention. See *In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed. Cir. 1995), cert. denied, 116

S.Ct. 1362 (1996), quoting from *In re LeGrice*, 301 F.2d 929, 936, 133 USPQ 365, 372 (CCPA 1962).

With respect to the applied prior art under 35 U.S.C. § 102(b), the examiner has explicitly demonstrated how the Ronk reference discloses each and every element set forth in the claims and how the pending claims read on the disclosure of the reference, hence the rejection is considered proper.

With regard to the rejections under 35 U.S.C 103, and with respect to any arguments that the secondary references to Berg et al., Lorenz et al., Solomon '184, Solomon '786, Brown et al., Lampropoulos et al., or Kirk cannot be bodily incorporated into the primary reference of Ronk, the test for obviousness is not whether the features of the reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the references make obvious to one of ordinary skill in the art. *In re Bozek*, 163 USPQ 545 (CCPA 1969); *In re Richman*, 165 USPQ 509 (CCPA 1970); *In re Beckum*, 169 USPQ 47 (CCPA 1971); *In re Sneed*, 218 USPQ 385. The suggestion to modify the art to produce the claimed invention need not be expressly stated in one or all of the references used to show obviousness and instead may be an implied suggestion. *Cable Electric Products. Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1025, 226 USPQ 881, 886 (Fed. Cir. 1985); *In re Sernaker*, 217 USPQ 1 (Fed. Cir. 1983); *In re Nilssen*, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988). It is not necessary that the references actually suggest, expressly or in so many words, the changes or improvements that applicant has made. Rather, the test for combining references is what the combined teachings of the references as a whole would have suggested to

those of ordinary skill in the art. *In re Sheckler*, 168 USPQ 716 (CCPA 1971); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971); *In re Young*, 159 USPQ 725 (CCPA 1968); *Cable Elec.*, 226 USPQ at 886-87. The motivation to combine can arise from the knowledge that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. *Miles Lab., Inc. v. Shandon Inc.*, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). In the instant application, the secondary references to Berg et al., Lorenz et al., Solomon '184, Solomon '786, Brown et al., Lampropoulos et al., or Kirk make obvious or suggest to one of ordinary skill in the art the provision of providing an opening in the plunger, a stand for the bone cement mixing receptacle, and measurement graduations on the receptacle.

While there must be some suggestion or motivation for one of ordinary skill in the art to combine the teachings of references, it is not necessary that such be found within the four corners of the references themselves; a conclusion of obviousness may be made from common knowledge and common sense of the person of ordinary skill in the art without any hint or suggestion in a particular reference. *In re Bosek*, 416 F.2d 1385, 163 USPQ 545 (CCPA 1969). Further, in an obviousness assessment, skill is presumed on the part of the artisan, rather than the lack thereof. *In re Sovish*, 769 F.2d 738, 226 USPQ 771 (Fed. Cir. 1985).

With respect to the applied references, the examiner has considered all of the disclosure of each reference for what it would have fairly taught one of ordinary skill in the art. *In re Boe*, 355 F.2d 961, 148 USPQ 507 (CCPA 1966). Additionally, the

specific teachings of each reference and the inferences which one skilled in the art would have reasonably been expected to draw from the disclosure has been taken into account. *In re Preda*, 401 F.2d 825, 159 USPQ (CCPA 1968). On the basis of the knowledge and level of skill in the art at the time of applicant's invention, as reflected by the applied references, the examiner concludes that the rejections under 35 USC 103 are well founded.

Applying the test for obviousness set forth in *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981), which is what the combined teachings of the references would have suggested to those of ordinary skill in the art, the examiner concludes that one having ordinary skill in the art would have found it prima facie obvious to have provided Ronk with an opening in the plunger, a stand for the bone cement mixing receptacle, and measurement graduations on the receptacle as taught by Berg et al., Lorenz et al., Solomon '184, Solomon '786, Brown et al., Lampropoulos et al., or Kirk.

With respect to any argument that the prior art must contain something to suggest the desirability of the combination, it is noted that to justify combining reference teachings in support of a rejection under 35 USC 103, it is not necessary that a device shown in one reference be capable of being physically inserted into the device shown in the other or that the prior art suggest expressly the changes or possible improvements the applicant has made. It is only necessary that knowledge clearly present in the prior art was applied. *In re Keller*, supra; *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983). The examiner has applied only knowledge clearly present in the prior art as

evidenced by Smith and Jones in the rejections of the pending claims and the rejections are thus proper.

Since the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been prima facie obvious at the time the invention was made, to a person having ordinary skill in the art, from the combined teachings of the references, the rejections under 35 USC 103(a) are considered proper.

In conclusion, the amendments made in the instant application are not deemed of a substantive nature to define over the prior art and thus all the rejections are considered proper.

Conclusion

11. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION

FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION. ANY RESPONSE FILED AFTER THE MAILING DATE OF THIS FINAL REJECTION WILL BE SUBJECT TO THE PROVISIONS OF MPEP 714.12 AND 714.13.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles E. Cooley whose telephone number is (571) 272-1139. The examiner can normally be reached on Mon-Fri. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles E. Cooley
Primary Examiner
Art Unit 1723

7 April 2005